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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,526	02/09/2001	Imre Kovesdi	206060	8376

23460            7590            01/13/2003

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TWO PRUDENTIAL PLAZA, SUITE 4900  
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1639

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/780,526	KOVESDI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Tomas Friend	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 September 2001.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-53 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **Detailed Action**

### **Change of Art Unit Designation**

**Please note:** The Art Unit location of this application in the PTO has changed from Art Unit 1627 to Art Unit 1639. To aid in matching papers to this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

### **Status of the Application**

Receipt is acknowledged of Information Disclosure Statements on 14 March 2001, 02 July 2001, and 04 September 2001 (Paper Nos. 4-6).

### **Status of the Claims**

Claims 1-53 are pending in the present application and are subject to restriction and election of species requirements.

### **Restriction**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, drawn to a library of viral vectors, classified in class 435, digest 24.
- II. Claims 13-15, drawn to a method of identifying functionally related coding sequences, classified in class 435, digest 4.
- III. Claims 16-35, drawn to a method of constructing a library of viral vectors via intermediate viral genomes and ligation, classified in class 435, digest 47.
- IV. Claims 36-53, drawn to a method of constructing a library of viral vectors involving linear DNA molecules and negative selection, classified in class 435, digest 47.

The inventions are distinct, each from the other because:

Inventions III and IV and Invention I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case both the methods of Inventions III and IV can be used to make the product of Invention I.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the library of Invention I can be used to screen for antigen-antibody interactions without comparing the activity the gene products encoded by the library with activity of other gene products.

Inventions II-IV are different and patentably distinct methods because they involve different method steps, starting materials, reagents, and/or reaction conditions and/or produce different products or results. For example the method of invention II results in the identification of functionally related coding sequences while the methods of Inventions III and IV result in the formation of a library of viral vectors. The method of Invention III includes method steps not found in the method of Invention IV such as forming intermediate viral genomes and ligating third DNA molecules into a pool of intermediate viral genomes. The method of Invention IV includes method steps not found in the method of Invention III such as the use of linear DNA molecules and negative selection genes.

Because these inventions are distinct for the reasons given above and

- a. have acquired a separate status in the art as shown by their different classification ;
- b. have different and separately burdensome: manual and/or computer: structure, name and bibliographical searches; and
- c. have divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under CFR 1.17(h).

### **Election of Species**

This application contains claims directed to patentably distinct species of the claimed inventions.

If applicants elect Invention I, applicants are required to elect species for each of the following A and B:

- A. Ultimate species of a first gene product (i.e. a specific gene product), AND
- B. Ultimate species of second gene product (i.e. a specific gene product).

If applicants elect Invention II, applicants are required to elect species for each of the following A-C:

- A. Ultimate species of a first gene product (i.e. a specific gene product),
- B. Ultimate species of second gene product (i.e. a specific gene product), AND
- C. Species of activity being compared.

If applicants elect Invention III, applicants are required to elect species for each of the following A-E:

- A. Species of first DNA molecule (including all functionally relevant fragments such as promoters, terminal repeats, selection markers, etc.),
- B. Species of second DNA molecule (including all functionally relevant fragments such as promoters, terminal repeats, selection markers, etc.),
- C. Species of viral vector (i.e. type of virus),
- D. Species of third DNA molecule (including all functionally relevant fragments such as promoters, terminal repeats, selection markers, etc.), AND
- E. Species of desirable feature (e.g. a specific activity associated with a specific gene product).

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If applicants elect Invention IV, applicants are required to elect species for each of the following :

- A. Species of (i) linear DNA molecule (including all functionally relevant fragments such as promoters, terminal repeats, selection markers, etc.),
- B. Species of (ii) recipient DNA molecule (including all functionally relevant fragments such as promoters, terminal repeats, selection markers, etc.),
- C. Species of viral genome (i.e. type of virus), AND
- D. Species of potentially desirable feature (e.g. a specific activity associated with a specific gene product).

The species are distinct, each from the other, because they have different structures with different chemical, physical, and/or pharmacological properties. Therefore, different issues of enablement and patentability apply to each species and each species represents patentably distinct subject matter.

Applicants are required under 35 U.S.C. 121 to elect single disclosed species internally consistent within each Invention for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicants traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend**, telephone number (703) 308-4548. The examiner's schedule is normally four, ten-hour days per week that includes Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Tomas Friend, Ph.D.  
07 January 2003



ANDREW WANG  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600